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| APPLICATION NO.                        | FILING DATE                    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|--------------------------------|----------------------|---------------------|------------------|
| 10/786,022                             | 02/26/2004                     | Liam Ward            | 12013/49901         | 2910             |
| 23838<br>KENYON & K                    | 7590 03/29/2007<br>ENYON L.L.P |                      | EXAM                | IINER            |
| 1500 K STREET N.W.                     |                                |                      | SWEET, THOMAS       |                  |
| SUITE 700<br>WASHINGTO                 | N, DC 20005                    |                      | ART UNIT            | PAPER NUMBER     |
|  |                                |                      | 3738                |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE |                                | MAIL DATE            | DELIVERY MODE       |                  |
| 3 MONTHS                               |                                | 03/29/2007           | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| Office Action Summary    Thomas J. Sweet  |   |  | Application No.                 | Applicant(s)                 |  |  |  |
|---|---|--|---------------------------------|------------------------------|--|--|--|
| Thomas J Sweet 3738  — The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Statement of time may be variable under the provision of 37 CFR 1139(e), in no event, however, may a veryly be timely filed state 50 (%) MONTHS from the mailing date of this communication.  If NO period for reply is specified above, the maximum statutory period vill apply and will apply est XI (%) MONTHS from the mailing date of this communication.  Failure to reply within the set or extended period for reply will, by statuts, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply occaved by the Office later than three ments after the mailing date of this communication, even if simely filed, may reduce any evented palent term adjustment. See 37 CFR 1.794(b).  Status  1) □ Responsive to communication(s) filled on 09 January 2007.  2a) □ This action is FINAL. 2b) □ This action is non-final.  3) □ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claim(s)  4) □ Claim(s) 1-6 and 9-13 is/are pending in the application.  4) □ Claim(s) 1-2. 4-6 and 10-13 is/are withdrawn from consideration.  5) □ Claim(s) 1-2. 4-6 and 10-13 is/are rejected.  7) □ Claim(s) 3 and 9 is/are objected to.  8) □ Claim(s) 3 and 9 is/are objected to by the Examiner.  Application Papers  9) □ The specification is objected to by the Examiner.  Application Papers  9) □ The drawing(s) filed on □ is/are: a) □ accepted or b) □ objected to by the Examiner.  Application Papers  9) □ The oath or declaration is objected to the drawing(s) be held in abeyance. See 37 CFR 1.121(d).  11) □ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form | Office Action Summary   |  | 10/786,022                      | WARD, LIAM                   |  |  |  |
| Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  Eduration of time may be available under the provision of 37 GPR. 1.136(a). In no event, however, may a reply be timely filed.  If NO peofid or reply is specified above, the maximum statutory period will apply and tile species (30) MONTHS from the mailing date of this communication.  Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONTED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any sammed patent term adjustment. See 37 CFR 1.704(b).  Status  1) ☑ Responsive to communication(s) filed on 09 January 2007.  2a) ☑ This action is FINAL. 2b) ☐ This action is non-final.  3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) ☑ Claim(s) 1-6 and 9-13 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  6) ☑ Claim(s) 3 and 9 is/are objected to.  8) ☐ Claim(s) 3 and 9 is/are objected to.  8) ☐ Claim(s) 3 and 9 is/are objected to by the Examiner.  Application Papers  9) ☐ The specification is objected to by the Examiner.  Application Papers  9) ☐ The oath or declaration is objected to by the Examiner.  Application Papers  9) ☐ The oath or declaration is objected to by the Examiner.  Application Papers  9) ☐ He oath or declaration is objected to by the Examiner.  Note the attached Office Action or form PTO-152.  Priority under 35 U.S.C. § 119  10 ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ All b) ☐ Some * c) ☐ None of  1. ☐ Certified copies of the prio               |   |  | Examiner                        | Art Unit                     |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.138(a), in no event, however, may a reply be timely filled early SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply whith the set or adented period for reply will, by statuto, cause the application to become ABANCONED (30 U.S. C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filled, may reduce any carried patent term sejectment. See 37 CFR 1.79(b).  Status  1)  |   |  | Thomas J. Sweet                 | 3738                         |  |  |  |
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| 2. Certified copies of the priority documents have been received in Application No  | 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) ☐ All b) ☐ Some * c) ☐ None of:   |  |                                 |                              |  |  |  |
|   |   |  |                                 |                              |  |  |  |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage   |   |  |                                 |                              |  |  |  |
|   |   |  |                                 |                              |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).   |   |  |                                 |                              |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.  |   |  |                                 |                              |  |  |  |
|   |   |  |                                 |                              |  |  |  |
|   |   |  |                                 |                              |  |  |  |
| Attachment(s)   |   |  |                                 |                              |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date.   |   |  |                                 |                              |  |  |  |
| 3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application  |   | 3) Information Disclosure Statement(s) (PTO/SB/08)  5) Notice of Informal Patent Application |                                 |                              |  |  |  |
| Paper No(s)/Mail Date 6) Other:   |   |  | 6)                              |                              |  |  |  |

Art Unit: 3738

### Response to Arguments

Applicant's arguments filed 01/09/2007 have been fully considered but they are not persuasive. The traverse of the withdrawal of claim 21 is not persuasive since no arguments were filed and is most since claim 21 was canceled.

Applicant's arguments, see page 4, filed 01/09/2007, with respect to 35 USC 112 (2) have been fully considered and are persuasive. The rejection of claim 9 under 35 USC 112 (2) has been withdrawn.

Applicant's arguments with respect to claims 1-6 and 9-13 have been considered but are moot in view of the new ground(s) of rejection.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6, 10, 11 are rejected under 35 U.S.C. 102(e) as being anticipated by White et al. (US 2004/0093076). White et al discloses a preassembled stent assembly (fig. 9) for insertion into a lumen of a patient, comprising:

a first stent (18) that provides internal scaffolding support for the lumen to resist radial compression;

Art Unit: 3738

a second stent (16) that provides internal scaffolding support for the lumen to resist radial compression; and

a delivery device (figs. 16-17 and 22-23) adapted to expand the stents simultaneously (as shown);

wherein the first stent is located at least substantially inside of the second stent prior to insertion into the patient (as shown), and each of the stents has a therapeutic coating on it [0086].

With regard to claim 10, the first stent is affixed to the second stent (by teeth such as in figs. 5-7 and 24-26).

With regard to claim 11, each of the first stent and the second stent has a patterned structure, and the patterned structure of the first stent is generally the same as the patterned structure of the second stent (helical).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-6 and 10-13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Brown (US 6,428,569). Brown discloses a stent assembly (figs. 2 or 5 or 7) for insertion into a lumen of a patient, comprising:

a first metallic (col 1, line 15) stent (such as 40) that provides internal scaffolding support for the lumen to resist radial compression and having a plurality of struts (col 1, lines 16-19) forming a

Art Unit: 3738

patterned structure;

a second metallic stent (such as 42) that provides internal scaffolding support for the lumen to resist radial compression and having a plurality of struts (col 1, lines 16-19) forming a patterned structure; wherein the first stent is located inside of the second stent (such as shown in fig. 7), and the stents are affixed to each other prior to insertion into the patient (col 3, lines 55-59); and wherein at least one of the first stent and the second stent has a coating on it (col 3, lines 55-59).

Brown remains silent as to having a delivery device adapted to expand the stents simultaneously. Brown inherently needs a delivery device to implant the stent (mechanically expanded, col 3, line 3). Additionally, Brown discloses that the stents are combined already for implanting simultaneously (col 4 lines 19-25) so, mechanically expandable stent combination would require a delivery device adapted to expand the stents simultaneously. It is also well known in that art of stents to utilize and delivery device adapted to expand a mechanically expandable stent (such as demonstrated by White et al. (US 2004/0093076) above) and therefore would also be prima fascia obvious.

With regard to claims 2 and 6, wherein each of the first stent and the second stent has a therapeutic coating on it (as disclosed in col 3, lines 55-59 it would).

With regard to claims 4 and 11, the patterned structure of the first stent is generally the same as the patterned structure of the second stent (fig. 2 and 5 show the same pattern).

With regard to claims 5 and 12, the patterned structure of the first stent is different from the patterned structure of the second stent (col 4, lines 17-18).

With regard to claim 10, the first stent is affixed to the second stent (col 3, lines 55-59).

Art Unit: 3738

With regard to claim 13, the first stent (40) has a different length from the second stent (42, as shown in fig. 7).

### Allowable Subject Matter

Claims 3 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 5:45am - 4:15pm, Tu-Th.

Art Unit: 3738

Page 6

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tjs

CORRINE MCDERMOTT
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